EXHIBIT F:

510(k) SUMMARY – (21 CFR § 807.92(c))

Submitter's Name and Contact Information
Pro•Duct Health, Inc.
1360 Willow Road, Suite 201
Menlo Park, California 94025
Telephone: 650.566.2330
Facsimile: 650.566.2345

Contact Person
Angela B. Soito, Director, Regulatory and Quality Affairs

Summary Preparation Date
March 31, 2000

Device Names

Trade Name:	Pro•Duct Health Micro-Stylet
Common Name:	Breast Duct Stylet
Classification Name:	Manual Surgical Instrument (21CFR § 878.4800)

Substantially Equivalent Devices
Substantial Equivalence was claimed to the Manan™ Galactography Kit.

Device Description
The Pro•Duct Health Micro-Stylet is a small metal device with a blunt tip. The total device length is approximately 5 cm with a 2.5 cm metal probe and a 2.5 cm polymer handle. The insertion tip outer diameter of the stylet is 0.008" which tapers to 0.025". The device is provided sterile and is intended for single use only.

Intended Use
The Pro•Duct Health Stylet is designed to dilate breast milk ducts prior to enhanced radiography (i.e., ductography) or ductal lavage procedures.

Technological Characteristics
The Pro•Duct Health Stylet is substantially equivalent to the Manan™ Galactography Kit. Both the subject and the predicate devices are comprised of similar materials and designs.

Data Supporting Substantial Equivalence
Pro•Duct Health conducted laboratory testing to demonstrate substantial equivalence. Laboratory testing was conducted to evaluate specific device performance parameters and, in some cases, to compare these results with those obtained with a predicate device. This testing supported the conclusion that the Pro•Duct Health Micro-Stylet is both safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Angela B. Soito
Director, Regulatory and Quality Affairs
Pro·Duct Health, Inc.
1360 Willow Road, Suite 201
Menlo Park, California 94025

Re: K001098
Trade Name: Micro-Stylet
Regulatory Class: II
Product Code: FMI
Dated: March 31, 2000
Received: April 4, 2000

Dear Ms. Soito:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT G:

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K001098

Device Name: Pro•Duct Health Micro-Stylet

Indications for Use:

The Pro•Duct Health Micro-Stylet is designed to dilate breast milk ducts prior to enhanced radiography (i.e., ductography) or ductal lavage procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DRO for CMO

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001098

Prescription Use X
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)